

June 22, 2017

Dr. Cheryl Ray Medical Director WPSIC 1717 W. Broadway Madison, WI 53701-1787

Submitted electronically to policycomments@wpsic.com

RE: Draft LCD – Wound Care (DL37228)

Dear Dr. Ray,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to Wisconsin Physician Service Insurance Corporation ("WPS") draft LCD on "Wound Care." The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org.

GENERAL COMMENTS

The Alliance has concerns regarding this WPS draft LCD on wound care. We believe that these changes if enacted have the potential of serious public health consequences for the wound care patients our members treat. Thus, we are recommending that WPS withdraw this policy and work with the Alliance physician specialty societies and clinical organizations and other stakeholders to establish an accurate well-balanced policy that is in line with clinical evidence and will not adversely impact patient care.

Our overarching issues include the following major points:

- Changes in the draft LCD seem to have no foundation in medical evidence or clinical practice guidelines and are not supported by citations in the bibliography especially in regards to the change in utilization parameters for both debridement and NPWT.
- Information contained within the draft LCD is inaccurate.
- There is confusing and at times conflicting language throughout this draft policy.
 We elaborate below on these important topics.

Changes in the draft LCD seem to have no foundation in medical evidence or clinical practice guidelines and are not supported by citations in the bibliography

• The Alliance is concerned that WPS created a draft policy in which the evidence used to support the many changes throughout this draft is not substantiated in the draft LCD.

First of all, it is our understanding that changes in a draft LCD should be based on the most relevant scientific evidence and clinical practice guidelines. In this WPS draft LCD, we do not find evidence cited in the bibliography ("Sources of Information and Basis for Decision") which supports recommendations that the contractor proposes and thus we submit that these proposed changes have no foundation in medical evidence and should be deleted.

According to the Program Integrity Manual (PIM) 13.7.1 the Evidence supporting an LCD "shall be based on the strongest evidence available". The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for <u>any</u> available evidence pertaining to the item or service in question.

Secondly, we have concerns that for the most part, much of the clinical evidence that is stated in the reference section of the bibliography is not topical or relevant to many of changes that are in this draft LCD (i.e., changes in utilization parameters for both debridement and NPWT).

Thirdly, it is difficult for those reading the LCD to understand which references validate the statements made in the draft LCD since there is no cross reference of the clinical references in the bibliography to the supporting statements.

Finally, it is problematic that WPS released this draft LCD without either conducting a thorough review of the published scientific evidence and the clinical practice guidelines so as to include it in this draft LCD or the contractor did conduct the review and chose to ignore this critically important information.

Therefore, WPS not only did not gather all the evidence that exists when developing this draft LCD, it used data that is not clinically sound or comports to the standards of practice based on clinical practice guidelines. The Alliance believes that the changes that have been made in this draft LCD challenge the standard of practice and WPS does not provide the necessary evidence to support the multiple changes made including but not limited to the utilization parameters for debridement and NPWT. In fact, WPS does not adhere to the above PIM guidelines for making such changes.

• The Alliance has concerns regarding the basis for which utilization parameters were established in that they do not adhere to current clinical practice guidelines and appear to be arbitrary.

It is our understanding that other MACs have based the utilization parameters identified in their draft LCD on claims data. While we do not know whether WPS has done the same, we have serious concerns regarding this since claims data can be both flawed and manipulated. It is also the interpretation of the claims data which could make for inappropriate utilization parameters.

We submit that any changes in medical coverage policy should be based on clinical evidence and not claims data. Thus the use of claims data is difficult not only for the MAC but for stakeholders to verify but also is not transparent and clinically relevant.

In addition, the PIM further states, "LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage". Claims data is not sufficient to make these changes, an incomplete and not current bibliography is not sufficient to validate these changes, nor is the lack of review of current clinical practice guidelines. For example, it is incumbent on WPS to provide the evidence that it used to base its decision for the changes in utilization for debridement and NWPT. That is not the case. The evidence provided in the bibliography does not substantiate the change in utilization nor is the evidence provided even complete or current.

- Since WPS did not include the most relevant and recent scientific evidence and clinical practice guidelines on these topics, we have included them in our comments. The Alliance would be pleased to discuss this information with the medical directors when we have the opportunity to work with WPS to establish its next version of this draft LCD. In reviewing the evidence for wound care, we wanted to make WPS aware of the following:
 - The evidence for wound care does exist; it is substantive and is representative of "real world" patients—the ones that our Alliance members treat on a daily basis. Patients with chronic wounds have multiple and serious co-morbidities that are not always represented in wound care RCT studies and data. These 'real-world' patients are often eliminated, through strict exclusion criteria, in RCT studies, as are patients with chronic renal disease, morbid obesity and auto-immune disease.

[Fife, C. E., & Carter, M. J. Wound care outcomes and associated cost among patients treated in US outpatient wound centers: Data from the US Wound Registry. *Wounds: a compendium of clinical research and practice*, 24(1), 10-17, 2012].

These factors can increase the duration and cost of wound care and may impact the effectiveness of advanced therapeutics in ways that cannot be ascertained by RCTs.

Moreover, the US Wound Registry (USWR), a Qualified Clinical Data Registry (QCDR), evaluated the exclusion criteria of all major randomized controlled trials (RCTs) performed in

wound care over a decade (1998-2008). It compared those exclusion criteria with the co-morbid conditions, wound characteristics and medications documented among 3,201 patients in 18 hospital-based outpatient wound centers. The data showed that approximately 75% of 'real world' patients would have been excluded from every major wound healing RCT that brought new products to market over that decade at the "first pass" before study related laboratories or tests would have been performed.

The USWR data confirms what the Alliance has been stating in our comments to regulatory agencies and Medicare Administrative Contractors (MACs); "RCTs are not able to evaluate the effectiveness of a wound care product or intervention, when more than half of patients are excluded from participation, greatly diminishing the applicability of RCT results to real world populations and evidence based medicine."

The Alliance believes that evidence can be established for coverage not only through RCTs but also through registry data, retrospective clinical studies (includes populations of patients with multiple co-morbid conditions that are commonly eliminated in most RCTs), scientific evidence and expert knowledge. Even if the studies are small, this approach is consistent with the widely accepted definition of evidence-based medicine and also adopted by the important organization Patient Centered Outcomes Research Institute (PCORI).

Therefore, as stated above, we would request that in reviewing wound care evidence, WPS recognizes that there may not be as many RCTs as in other health care sectors such as cardiology due to the exclusion of more than half of patients from participation; therefore, one should accept as appropriate real world evidence that would be more inclusive of wound care patients identified above such as retrospective studies.

The Alliance has separated our specific comments into two distinct sections. The first addresses our 5 most significant specific concerns with this draft policy. The second section addresses additional concerns we have with language identified throughout the policy which will be presented in the order those provisions appear in the draft LCD rather than in order of importance. Our specific comments follow.

SPECIFIC COMMENTS

<u>Section 1 – Five Significant Specific Concerns</u>

1. Utilization parameters- Debridement

Language in Policy – *It is expected only one debridement involving true removal of muscle and/or bone to be required for management of most wounds within a 12 (twelve) month.*

Concerns – The Alliance disagrees with the statement above for these reasons:

- It may be necessary to remove muscle and/or bone more than once in a 12 month period. For example, on day one, muscle only is removed from the patient with the hope of not needing to remove bone. However, the ulcer deteriorates and on day 28, it is necessary to remove bone. In this situation, the patient would not be covered for the second debridement. Another example of when additional debridements would be necessary could include situations when the ulcer gets bigger or even when more muscle/bone becomes non-viable some time after the first muscle/bone debridement. A patient can have recurrent ulcers within the calendar year, and/or have recalcitrant ulcers that can require more than one muscle and/or bone debridement in a year. To limit the debridement to only one is not clinically sound.
- WPS does not indicate that this limitation (which we do not agree with to begin with) is per patient per wound. This could be a significant issue if the Medicare beneficiary/patient has more than one ulcer that requires a muscle or bone debridement. WPS would not know this based on the claims data that they receive from the hospital or physician since claims data isn't that transparent and therefore one debridement would not be sufficient for that patient.

According to WPS (as stated in the draft policy under Coverage Guidance) the *Goals of Debridement include* – "remove obstructive tissue, decrease risk of infection, promote wound healing, prevent further complications". The Alliance agrees with these goals of debridement statement. However, setting an arbitrary limitation of only one muscle and/or bone debridement for Medicare beneficiaries with chronic wounds is inconsistent with this statement.

There are systematic reviews, clinical care guidelines, and independent studies all which conclude that wound closure was more rapid in wounds that underwent frequent debridement. No maximum number of debridement was identified by these data.

Recommendation: The Alliance recommends that WPS not provide limitations on the number of debridement in which a clinician can perform on their patient. The clinical evidence and consensus documents that exist suggest that the more frequent the debridement the better the chance for a patient's wound to close. Therefore, the necessity for a debridement involving removal of muscle and/or bone should be based on the clinical condition of the patient and the expertise of the clinician.

Evidence to Support Concerns and Recommendations

Wilcox JR, Carter MJ, Covington S. Frequency of Debridements and Time to Heal; A Retrospective Cohort Study of 312 744 Wounds. JAMA Dermatol. 2013;149(9):1050-1058. http://jamanetwork.com/journals/jamadermatology/fullarticle/1720508

Steed DL, Donohoe D, Webster MW, Lindsley L. Effect of extensive debridement and treatment on the healing of diabetic foot ulcers. Diabetic Ulcer Study Group. J Am Coll Surg 1996;183(1): 61-64. https://www.ncbi.nlm.nih.gov/pubmed/8673309

Warriner, Robert A. III MD, ABPM/UHM, FACA, FCCP, FCCWS; Wilcox, James R. BSN; Carter, Marissa J. PhD, MA; Stewart, Deborah G. MD. More Frequent Visits to Wound Care Clinics Result in Faster Times to Close Diabetic Foot and Venous Leg Ulcers. Advances in Skin & Wound Care: November 2012:25(11): 494-501.

Consensus Guidance Documents to Support Concerns and Recommendations

Lavery LA, et al. WHS guidelines update: Diabetic foot ulcer treatment guidelines. Wound Repair Regen 2016; 24:112-26

Hingorani A, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg 2016; 63:3S-21S.

National Institute of Clinical Excellence. Diabetic foot problems: Prevention and management. Updated January 2016. https://www.nice.org.uk/guidance/ng19/chapter/Patientcentred-care Many consensus guidelines, including those by the Wound Healing Society, the Society for Vascular Surgery, and the United Kingdom's National Institute of Clinical Excellence (NICE), the recommend debridement as often as necessary as best practice for wound care, without limitation of the number.

2. Utilization parameters- NPWT services

Language in Policy – (**p. 6**) *No more than 6 NPWT services in a four month period will be considered reasonable and necessary.*

Concerns -

- As previously stated in our general concerns, the Alliance is concerned that WPS has set arbitrary utilization parameters without providing any supportive clinical evidence or standard clinical practice guidelines to substantiate the changes made. In fact, the utilization parameters suggested by WPS are specifically not substantiated in their evidence. WPS is required to be transparent when creating medical policies. The evidence utilized in making any changes to medical policy must be provided in the bibliography so stakeholders can review the literature reviewed. However, WPS has not been transparent and has not provided such evidence in the bibliography.
- Additionally, there is a question as to whether parameters even need to be set. NPWT dressings should be changed based upon the condition of the wound as well as the manufactures recommendation in their instructions for use. The proposed utilization parameters are completely arbitrary and can result in increased risk of infection and worsened outcomes.
- Furthermore, while WPS does not specifically call out disposable NPWT versus traditional DME NPWT, the HCPCS codes cited at the end of this draft policy suggest that WPS will cover

disposable NPWT and that the utilization parameters identified in the draft policy applies to both traditional and disposable NPWT. The Alliance supports the coverage of both traditional and disposable NPWT as a treatment option for our patients.

Recommendations: The Alliance supports and agrees with coverage under this policy of disposable NPWT. However, the utilization parameters identified in this draft policy are arbitrary and not based on clinical evidence. As such, the Alliance recommends that WPS eliminate the references to utilization parameters for NPWT.

Evidence to Support Concerns and Recommendations

Argenta, L. C. and M. J. Morykwas. 1997. "Vacuum-Assisted Closure: A New Method for Wound Control and Treatment: Clinical Experience." *Annals of Plastic Surgery* 38(6):563–76; discussion 577.

Birke-Sorensen, H. et al. 2011. "Evidence-Based Recommendations for Negative Pressure Wound Therapy: Treatment Variables (Pressure Levels, Wound Filler and Contact Layer) - Steps towards an International Consensus." *Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS* 64 Suppl:S1–16.

Hurd, Theresa, Alan Rossington, Paul Trueman, and Jennifer Smith. 2017. "A Retrospective Comparison of the Performance of Two Negative Pressure Wound Therapy Systems in the Management of Wounds of Mixed Etiology." *Advances in Wound Care* 6(1):33–37.

Krug, E. et al. 2011. "Evidence-Based Recommendations for the Use of Negative Pressure Wound Therapy in Traumatic Wounds and Reconstructive Surgery: Steps towards an International Consensus." *Injury* 42 Suppl 1:S1-12.

Martin, R. 2016. "PubMed Search 16th September 2106 Negative Pressure Wound Therapy." PubMed.

Vig, S. et al. 2011. "Evidence-Based Recommendations for the Use of Negative Pressure Wound Therapy in Chronic Wounds: Steps towards an International Consensus." *Journal of Tissue Viability* 20 Suppl 1:S1-18.

Guidelines To Support Concerns and Recommendations

- * World Union of Wound Healing Society (WUWHS), Principles of best practice: Vacuum assisted closure: recommendations for use. A Consensus Document. 2008
- * Guidelines of Managing Pressure Ulcers with Negative Pressure Wound Therapy, Adv Skin Wound Care, 2004
- * http://www.usaisr.amedd.army.mil/cpgs/CCATCPGNegativePressureWoundTherapyDec2013.pdf

3. Rate of Closure

Language in policy: Medicare expects that with appropriate care: Wound volume or surface dimension should decrease by at least 10 percent per month or Wounds will demonstrate granulation tissue advancement of no less than 1 mm/week

Concerns: The Alliance has significant issues with the wording in this section for the following reasons:

- There is no specific set standard of care that supports either the statement "that the wound should decrease by at least 10 per cent per month", OR "that wounds will demonstrate a margin of advancement of no less than 1 mm/week".
 - First, wounds will not heal 1mm/week in the initial 30 day time frame. The wound is in the inflammatory and early proliferative phase of healing at this time frame and much of the improvement is at the biochemical and cellular level and not measurable at the macroscopic level. Margin migration will not occur until a wound is fully granulated (depth fully eliminated) and epithelial migration can proceed. Surface area can reduce at this early time frame but it is secondary to contraction which can be asymmetrical and difficult to measure as described in the policy. Furthermore, the 1 mm/week does not take into account the initial size of the wound or any co-morbidities or individual patient medical circumstances presented.
- As providers, clinicians and researchers, our members are not aware of any evidence that would support either the statement "with appropriate care, wound volume or surface dimension will demonstrate advancement of no less than 1mm/week" or that "with appropriate care, wound volume or surface dimension should decrease by at least 10 per cent per month" and do not believe that it is appropriate for a value to be arbitrarily established absent scientific evidence to support it. The medical literature does not provide a rate of 10% per month or 1mm/week and no reference was provided by WPS to substantiate this requirement.

While there are specific measureable changes that can be utilized for establishing the status of a wound that is healing, setting specific values should not be utilized – especially when they are arbitrarily established. Each wound type heals at a different rate. Patients heal at a different rate depending on their overall medical status. Therefore, setting arbitrary rates of closure is not in the best interest of the patient and is not established in the clinical literature.

Recommendations: Since the Alliance objects to the use of values to determine wound healing, we recommend that:

• WPS remove any references to value within the indications portion of the policy. "1 mm/week and 10 per cent per month should be deleted.

• WPS should provide the citations used to set the healing values presented in the draft LCD, including references for the studies that were utilized to develop this policy.

4. Photographic Documentation

Language in Policy – Photographic documentation of wounds immediately before and after debridement is recommended for prolonged or repetitive debridement services (especially those that exceed five debridements per wound). Photographic documentation is required for payment of more than five extensive debridements (beyond skin and subcutaneous tissue) per wound

Concerns: The Alliance has several concerns with the wording in this section.

- There is conflicting language. In one sentence, WPS is recommending photographic documentation, and then in the next, proceeds to require it for payment. This is contradictory.
- The Alliance believes that WPS should recommend photographic documentation but not require it. It is too costly for providers to take photographs on a wound both before and after debridement. Unless Medicare is willing to increase the RVU amount and the relative weight for the hospital APC payment for the clinician's time, this should not be a requirement. Providers already are documenting medical necessity as a requirement for payment. Requiring photographs is too extreme and costly.
- Additionally, the Alliance believes that recommending photographs immediately before and after the debridement is excessive one or the other should suffice if any should be required at all.

Recommendation: The Alliance recommends that the sentence be modified to read, "Photographic documentation of wounds either immediately before or immediately after debridement is recommended for prolonged or repetitive debridement services (especially those that exceed 5 debridements per wound).

5. Conditions Which Must Be Met To Receive Debridement Services Are Too Limited

Language in the policy:

At least ONE of the following conditions must be present and documented:

- Pressure ulcers, Stage III or IV,
- Venous or arterial insufficiency ulcers,
- Dehiscenced wounds,
- Wounds with exposed hardware or bone,
- Neuropathic ulcers,
- Complications of surgically-created or traumatic wound where accelerated granulation therapy is necessary which cannot be achieved by other available topical wound treatment.

Concern:

There are 1,747 distinct ICD-10 diagnosis codes of wounds and ulcers that required debridement. To limit the conditions that must be present in order for a clinician to be permitted to perform a debridement is clinically unsound and unreasonable. A patient who requires a debridement of a wound does not always have one of the conditions present that WPS has identified in this draft policy. There are many other conditions that should be included in this list including but not limited to the following:

- Stage 1 or 2 Pressure Ulcers
- Necrotizing Fasciitis
- Osteomyelitis
- Pyoderma Grangrenosum
- Ischemic ulcers secondary to Sickle Cell Anemia
- Burns
- Vasculitic ulcers

Recommendation: The Alliance does not agree with the terminology utilized in this draft policy and recommends eliminating the limitations to the conditions that a patient have in order to receive debridement services under this policy.

<u>Section 2 – Additional Specific Problematic Language in the Draft LCD</u>

In this section of our comments we have identified other areas in the policy in which the Alliance has specific concerns. These comments have been provided in the order the specific provision/language shows up in the policy.

Limitations Section

1. Language in Policy – (p. 5) The following services are considered to be not reasonable and necessary wound debridement services:

Removal of necrotic tissue by cleansing, scraping (other than by a scalpel or a curette), chemical application, or dry-to-dry or wet-to-dry dressing

Concern –The only service listed that is not considered a debridement and therefore accurate to be listed here is cleansing. The other services listed are considered a debridement and are also highlighted by WPS when discussing debridement. Therefore, placement in this section contradicts what was contained in the policy previously.

Recommendation – The Alliance recommends that this language be eliminated as it is inaccurate and contradicts what is previously contained in the policy

2. Language in Policy (p. 5) - Paring or cutting of corns or non-plantar calluses. Skin breakdown under a dorsal corn that begins to heal when the corn is removed and shoe pressure eliminated is not considered an ulcer and does not require debridement unless there is extension into the subcutaneous tissue.

Concern -The Alliance disagrees with the statement made above. Specifically, having a dorsal "corn" in and of itself would not require debridement. However, once, as the policy states, there is "skin breakdown under a dorsal corn" – it is no longer just a "corn". Once there is skin breakdown, it becomes an ulcer. Many patients have an abscess which require debridement, local lavage and systemic and/or topical antibiotics and wound care. Many patients' ulcers begin as hyperkeratosis and eventually cause deep tissue necrosis resulting in wounds where the apoeneurosis are exposed. As such, the Alliance believes that the statement made in the policy is inaccurate and should be removed.

Recommendation: The Alliance recommends that this language be deleted from the policy as it is inaccurate. Once there is skin breakdown, a dorsal corn is considered an ulcer and may require debridement.

3. Language in the Policy (p. 5) – While mechanical debridement is a valuable technique for healing ulcers, it does not qualify as debridement services.

Concerns:

- Mechanical debridement is a debridement service and should qualify as such. Other AB
 MACs have included mechanical debridement services in their LCD policies, as it is a
 valuable and effective service. To say that mechanical debridement does not qualify as a
 debridement service is simply inaccurate and not clinically sound policy.
- Furthermore, it contradicts what is included within the CPT code. By definition, mechanical debridements are classified as a non-selective debridement. Non-selective debridements are a covered service under CPT code 97602 which states:

Mechanical Debridement: Wet-to-dry or dry-to-dry dressings may be used with wounds that have a high percentage of necrotic tissue. Wet-to-dry dressings should be used cautiously as maceration of surrounding tissue may hinder healing.

Recommendation: The Alliance recommends that WPS eliminate the following sentence from the policy, "While mechanical debridement is a valuable technique for healing ulcers, it does not qualify as debridement services". Mechanical debridement is classified as a non-selective debridement within CPT code 97602.

Documentation Requirements

Language in Policy – (p. 7) When wound care is provided by the Physical Therapist, for both in and

out patient wound care, the medical record is required to have the following documentation:

- *Physician order(s) for physical therapy (PT)/wound care services.*
- Initial evaluation of PT/wound care services.
- Wound characteristics such as diameter, depth, color, presence of exudates or necrotic.
- Previous wound care services administered including date and modalities of treatment.
- Plan of treatment for PT/wound care services.
- Weekly progress notes to include current wound status, measurements (including size and depth), and the treatment provided.
- Description of instrument used for selective or sharp debridement (i.e. forceps, scalpel, scissors, tweezers, high-pressure water jet, etc.).
- Certification/recertification for PT/wound care services.
- Actual minutes provided to support each timed service/HCPCS provided.

Concern: The Alliance is concerned that physical therapists are being singled out as having to provide additional documentation than all other practitioners. The documentation requirements that have been provided in this draft policy should suffice and WPS should not create additional requirements solely for physical therapists. Physical therapists are well trained to provide wound care treatments. When providing wound care treatment, physical therapists already provide complete documentation that safeguards the patient and demonstrates to Medicare that services provided were reasonable and necessary. Additional requirements are unnecessary and only subject physical therapists to administrative burden.

Recommendations: The Alliance recommends that WPS eliminate the special documentation requirements for physical therapists and instead simply subject physical therapists to the same documentation requirements that are required of any other practitioner providing wound care treatment. As such, the documentation requirements that have been provided in the draft policy should be sufficient for all practitioners.

2018 ICD-10-CM Code Updates

The World Health Organization (WHO) has included additional ICD-10 codes in their 2018 code updates. The L97 and L98 code additions will go into effect for outpatient encounters on or after October 1, 2017. Additional codes were added for proper coding to the highest degree of specificity for (1) muscle involvement without evidence of necrosis; (2) bone involvement without evidence of necrosis; and (3) with other specified severity. These code categories are applicable for patients seen in hospital outpatient departments and physician offices and should be added to the WPS list of ICD-10 codes that support medical necessity included in the final Wound Care LCD if the effective date of the final LCD is on or after October 1, 2017.

CONCLUSION

The Alliance appreciates the opportunity to provide you with our comments. As stated in the beginning of our comments, due to our concerns with this draft LCD, we are recommending that WPS withdraw this policy and work with the Alliance physician specialty societies and clinical organizations and other stakeholders to establish an accurate well-balanced policy that is in line with clinical evidence and will not adversely impact patient care.

If you have any questions, please do not hesitate to contact me.

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Executive Director